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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,516	02/11/2005	Hans Loibner	4518-0109PUS1	1154

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EXAMINER	
SANG, HONG	
ART UNIT	PAPER NUMBER
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
31 DAYS	01/03/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 31 DAYS from 01/03/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/524,516	LOIBNER ET AL.	
	Examiner	Art Unit	
	Hong Sang	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RE: Loibner et al.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8, drawn in part to a kit comprising: a) an antigen comprising at least one epitope of a cellular surface protein, and b) an antigen comprising at least one epitope of an aberrant protein glycosylation.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single antigen for a) from claims 5-6 and 8 (i.e. cellular adhesion protein, EpCAM, NCAM, CEA, a surface receptor, EGF receptor family, CD55 receptor, transferring receptor, p-glycoprotein, and Her-2/neu), and a single antigen for b) from claim 7 (i.e. Lewis antigens, Lewis y, Lewis b, sialyl-Tn and Globe H). This election should not be construed as an election of species. This is a restriction requirement.

Group II, claim(s) 1-8, drawn in part to a kit comprising: a) an antigen comprising at least one epitope of a cellular surface protein, and b) an antibody directed against the aberrant protein glycosylation.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single antigen for a) from claims 5-6 and 8 (i.e. EpCAM, NCAM, CEA, EGF receptor family, CD55 receptor, transferring receptor, p-glycoprotein, and Her-2/neu), and a single antigen for b) from claim 7 (i.e. Lewis y, Lewis b, sialyl-Tn and Globe H). This election should not be construed as an election of species. This is a restriction requirement.

Group III, claim(s) 1-8, drawn in part to a kit comprising: a) an antibody directed against the cellular surface protein, and b) an antigen comprising at least one epitope of an aberrant protein glycosylation.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single antigen for a) from claims

5-6 and 8 (i.e. cellular adhesion protein, EpCAM, NCAM, CEA, a surface receptor, EGF receptor family, CD55 receptor, transferring receptor, p-glycoprotein, and Her-2/neu), and a single antigen for b) from claim 7 (i.e. Lewis antigens, Lewis y, Lewis b, sialyl-Tn and Globe H). This election should not be construed as an election of species. This is a restriction requirement.

Group IV, claim(s) 1-8, drawn to a kit comprising: a) an antibody directed against the cellular surface protein, and b) an antibody directed against the aberrant protein glycosylation.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single antigen for a) from claims 5-6 and 8 (i.e. cellular adhesion protein, EpCAM, NCAM, CEA, a surface receptor, EGF receptor family, CD55 receptor, transferring receptor, p-glycoprotein, and Her-2/neu), and a single antigen for b) from claim 7 (i.e. Lewis antigens, Lewis y, Lewis b, sialyl-Tn and Globe H). This election should not be construed as an election of species. This is a restriction requirement.

Group V, claim(s) 9-13, drawn in part to a method for the immunologic determination of tumor cells of a solid tumor or disseminated tumor cells of a cancer disease which comprises exposing a sample from a cancer patient to i) an antigen comprising at least one epitope of a cellular surface protein, and ii) an antigen comprising at least one epitope of an aberrant protein glycosylation.

Group VI, claim(s) 9-13, drawn in part to a method for the immunologic determination of tumor cells of a solid tumor or disseminated tumor cells of a cancer disease which comprises exposing a sample from a cancer patient to i) an antigen comprising at least one epitope of a cellular surface protein, and ii) an antibody directed against the aberrant protein glycosylation.

Group VII, claim(s) 9-13, drawn in part to a method for the immunologic determination of tumor cells of a solid tumor or disseminated tumor cells of a cancer disease which comprises exposing a sample from a cancer patient to i) an antibody directed against the cellular surface protein, and ii) an antigen comprising at least one epitope of an aberrant protein glycosylation.

Group VIII, claim(s) 9-13, drawn in part to a method for the immunologic determination of tumor cells of a solid tumor or disseminated tumor cells of a cancer disease which comprises exposing a sample from a cancer

patient to i) an antibody directed against the cellular surface protein, and ii) an antibody directed against the aberrant protein glycosylation.

Group IX, claim(s) 14, drawn in part to a method for immunologic selection of a tumor-specific target antigen or of antibodies direct against the target antigen which comprises exposing a sample from a cancer patient to a) an antigen comprising at least one epitope of a cellular surface protein, and b) an antigen comprising at least one epitope of an aberrant protein glycosylation.

Group X, claim(s) 14 and 17, drawn in part to a method for immunologic selection of a tumor-specific target antigen or of antibodies direct against the target antigen which comprises exposing a sample from a cancer patient to a) an antigen comprising at least one epitope of a cellular surface protein, and b) an antibody directed against the aberrant protein glycosylation.

Group XI, claim(s) 14 and 17, drawn in part to a method for immunologic selection of a tumor-specific target antigen or of antibodies direct against the target antigen which comprises exposing a sample from a cancer patient to a) an antibody directed against the cellular surface protein, and b) an antigen comprising at least one epitope of an aberrant protein glycosylation.

Group XII, claim(s) 14 and 17, drawn in part to a method for immunologic selection of a tumor-specific target antigen or of antibodies direct against the target antigen which comprises exposing a sample from a cancer patient to a) an antibody directed against the cellular surface protein, and b) an antibody directed against the aberrant protein glycosylation.

Group XIII, claim(s) 15-16, drawn to an antigen composition which comprises a neoepitope or its mimic.

Group XIV, claim(s) 18, drawn to an antibody composition with specificity for a neo-epitope.

Group XV, claim(s) 19-22, drawn to a diagnostic agent comprising a reagent for determining an immune reaction with components a) and b), wherein a) is an antigen comprising at least one epitope of a cellular surface protein, and b) is an antigen comprising at least one epitope of an aberrant protein glycosylation.

Group XVI, claim(s) 19-22, drawn to a diagnostic agent comprising a reagent for determining an immune reaction with components a) and b), wherein a) is

an antigen comprising at least one epitope of a cellular surface protein, and b) is an antibody directed against the aberrant protein glycosylation.

Group XVII, claim(s) 19-22, drawn to a diagnostic agent comprising a reagent for determining an immune reaction with components a) and b), wherein a) is an antibody directed against the cellular surface protein, and b) is an antigen comprising at least one epitope of an aberrant protein glycosylation.

Group XVIII, claim(s) 19-22, drawn to a diagnostic agent comprising a reagent for determining an immune reaction with components a) and b), wherein a) an antibody directed against the cellular surface protein, and b) is an antibody directed against the aberrant protein glycosylation.

2. The inventions listed as Groups I-XVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature linking the groups I-XVIII appears to be a kit or composition comprising: a) an antigen comprising at least one epitope of a cellular surface protein, or an antibody directed against the cellular surface protein, and b) an antigen comprising at least one epitope of an aberrant protein glycosylation, or an antibody directed against the aberrant protein glycosylation (see claim 1). The kit or composition of claim 1 cannot be a special technical feature under PCT Rule 13.2 because it is shown in the prior art. WO 00/06605 (Pub. Date 2/10/2000, IDS) teaches a heterominibody which comprises a single chain antibody specific against Lewis Y and a single chain antibody specific against CD80, which is a cell surface antigen present in peripheral blood monocytes and dendritic cells (see page 52, Example 3). As the instant claims encompass components that can be linked (see instant specification, page 17, 2nd paragraph), the teachings of WO 00/06605 anticipate the instant claim 1. Therefore the technical

feature linking the inventions is not novel and does not provide contribution over the prior art. Therefore, unity of invention is lacking and the inventions are deemed to be separate.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hong Sang, Ph.D.
Art Unit 1643
Dec. 22, 2006

CHRISTOPHER H. YAEN
PRIMARY EXAMINER